JAN 2 7 2012

510(k) Summary K102383

Purpose for Submission:
Addition of Palm testing (alternate site) to existing product.

Analyte:
Whole blood Glucose

Type of Test:
Quantitative (electrochemical biosensor)

Applicant:
Cambridge Sensors Limited

Units 9 & 10
Cardinal Park
Godmanchester
Huntingdon
Cambs PE29 2XG
United Kingdom

Contact Name: Dr. Bernadette Yon-Hin

Date: 24th January 2012

Proprietary and names:

microdot*® *Home Blood Glucose Monitoring system :
consisting of three products
microdot*® *Home Blood Glucose Meter
microdot*® *Home Test Strips
***microdot*®** Control solutions

Regulatory Information:

Regulation section:
21 CFR § 862.1345, Blood Glucose Test System

Classification:
Class II, Class I

Product Code:
NBW, Blood Glucose test system, over the counter
LFR, Glucose Dehydrogenase, glucose

Panel:
Clinical chemistry (75)

Intended Use

Intended use(s):
See indication(s) for use below

Indication(s) for use:

The ***microdot*** ® ***Home*** Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use only), by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is intended for "single patient-home use" only and should not be shared. It should be used only for testing fresh capillary whole blood samples from a fingerstick or palm for glucose (sugar). Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for use on neonates or in the diagnosis of or screening for diabetes mellitus.

The system consists of the ***microdot*** ® ***Home*** Blood Glucose meter, ***microdot*** ® ***Home*** Test Strips and ***microdot*** ® Control solutions.

microdot ® ***Home*** Test Strips
The ***microdot*** ® ***Home*** Test strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick or palm.

Special conditions for use statements(s):

This product is intended for over-the-counter.
Fingerstick testing only (no palm testing) should be performed if blood glucose level is changing rapidly as follows:

- Within 2 hours after a meal
- Within 2 hours after insulin dosing
- Patients with a history of hypoglycaemia, experiencing symptoms of low sugar or suffer from hypoglycaemic unawareness.

Special instrument requirements:

microdot ® ***Home*** Blood Glucose Meter

Device Description:

The ***microdot*** ® ***Home*** Blood Glucose Monitoring System consists of the ***microdot*** ® ***Home*** Blood Glucose Meter, ***microdot*** ® ***Home*** Test Strips, ***microdot*** ® Control Solutions and a commercially available (510(k) cleared) lancing device and lancets. A clear cap is provided with the lancing device for alternate site testing on the palm. ***microdot*** ® ***Home*** Blood Glucose Monitoring System is for a single patient use only. The meter and lancing device must not be shared with anyone.

microdot ® ***Home*** is an auto code system. The meter turns on upon insertion of the strip, a blood sample from the finger or palm is applied to the test strip and after 10 seconds, the plasma glucose result is displayed on the screen in mg/dL only.

microdot ® ***Home*** Blood Glucose Monitoring System is substantially equivalent in form, firmware, fundamental scientific technology and specifications as the predicate system, ***microdot*** ® Xtra Blood Glucose Monitoring System. It relies on quantitative

electrochemical biosensor technology to measure current generated on disposable test strips.

The strip remains unchanged since the last submission approval, ***microdot***® Xtra Blood Glucose Monitoring System (k083273). The Test Strip manufacturing and performance characteristics are unchanged. The test strips are designed to quantitatively measure glucose in fresh capillary blood from the fingertip by persons with diabetes.

Substantial Equivalence Information:

Predicate device name (s):

microdot® Blood Glucose Monitoring System, 510(k) Number :k070524

microdot® Xtra Blood Glucose Monitoring System, 510(k) Number:k083273
Comparison with predicate:

microdot® ***Home*** Test Strips share the same design, functionality, raw materials and manufacturing process as. ***microdot***® Xtra Test Strips.

Comparison to Predicate Devices:

	Device 1	***Predicate 1***	***Predicate 2***
Product Name	***microdot***® ***Home***	***microdot***® (k070524)	***microdot***® Xtra (k083273)
Code	No code number	Code Number for each lot of strips	No code number
Enzyme	Glucose Dehydrogenase/NAD	Same	Same
Sample	Fresh Capillary whole blood	Same	Same
Blood Source	***Finger, Palm***	***Finger***	***Finger***
Test Principle	Electrochemical Biosensor	Same	Same
Calibration	Plasma equivalent	Same	Same
Sample volume	600nanoliters	Same	Same
Temperature and humidity range	10°- 40°C 10-90% RH	Same	Same
Hematocrit range	30-50%	Same	Same
Measurement Range	25 – 525 mg/dL	Same	Same
Control Solution	Low, Normal, High	Same	Same

Standard/Guidance Document referenced (if applicable):
ISO15197:2003: *in vitro* diagnostic test systems- requirements for blood-glucose monitoring systems for self testing in managing diabetes mellitus (Section 8: User Performance)

Test Principle

The test is based on the enzymatic conversion of glucose in the sample to gluconolactone, with concomitant reduction of the enzyme cofactor NAD^+ to NADH. The NADH is re-oxidised to NAD^+ by the mediator compound which in turn becomes reduced; re-oxidation of the mediator by the meter induces a micro current to flow, and the size of this micro current is directly proportional to the amount of glucose in the sample. Unlike PQQ dependent Glucose Dehydrogenase, the NAD-dependent Glucose Dehydrogenase enzyme used in the ***microdot® Home*** test strips is specific to glucose and has no interference from galactose and maltose.

Performance Characteristics

1. Analytical Performance

   Precision/ Reproducibility
   Established in original submission (k070524)

   Linearity/assay reportable range
   Established in original submission (k070524)

   Traceability, Stability, Expected values (controls, calibrators, or methods)
   Established in original submission (k070524)

   Detection Limit
   Established in original submission (k070524)

   Analytical Specificity
   Established in original submission (k070524)

   Assay Cut-off
   Not applicable

2. Comparison Studies

   Comparison with predicate device
   Established in original submission (k070524)

   Alternate Site Testing at Palm

   A consumer study was performed with 152 diabetics testing themselves both at finger and alternate site and healthcare professionals testing at finger only to see if the results obtained at the alternate site is comparable with the finger. The diabetics obtained the samples and carried out the tests using the instructions provided. The samples ranged from 48 to 367 mg/dL. The palm results were comparable to finger results.

Summary of Accuracy Results for all sites tested			
Sites tested	For glucose levels < 75mg/dL		
	Within +/- 5mg/dL	Within +/- 10mg/dL	Within +/- 15mg/dL
Subject Palm Accuracy vs YSI	0 (3) 0%	2 (3) 67%	3 (3) 100%
Subject finger Accuracy vs YSI	1 (3) 33%	3 (3) 100%	3 (3) 100%
HCP finger Accuracy vs YSI	1 (3) 33%	3 (3) 100%	3 (3) 100%

Summary of Accuracy Results for all sites tested				
Sites tested	For glucose levels ≥ 75mg/dL			
	Within +/- 5%	Within +/- 10%	Within +/- 15%	Within +/- 20%
Subject Palm Accuracy vs YSI	61 (149) 41%	109 (149) 73%	134 (149) 90%	146 (149) 98%
Subject finger Accuracy vs YSI	76 (149) 51%	121 (149) 81%	138 (149) 93%	144 (149) 97%
HCP finger Accuracy vs YSI	62 (149) 42%	116 (149) 78%	138 (149) 93%	146 (149) 98%

3. Disinfection Studies

Dispatch Hospital Cleaner Disinfectant wipes with Bleach with EPA registration # 56392-8 was validated demonstrating complete inactivation of Hepatitis B virus. It was demonstrated that there was no change in performance or in the external materials of the meter and lancing device for a minimum of 375 cycles equivalent to a pre-clean and disinfection cycle of once per week for 5 years for a single patient use only meter.

Conclusion

The study supports substantial equivalence to a predicate device and the addition of palm testing as an alternate testing site for blood glucose testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

CAMBRIDGE SENSORS LIMITED
c/o Dr. Bernadette Yon-Hin
Units 9 & 10 Cardinal Park
Godmanchester
Huntingdon, Cambridgeshire
United Kingdom PE29 2XG

JAN 27 2012

Re: k102383
Trade Name: microdot® Home Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: January 5, 2012
Received: January 9, 2012

Dear Dr. Yon-Hin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k102383

Device Name: ***microdot*® *Home*** Blood Glucose Monitoring System

Indication for Use:

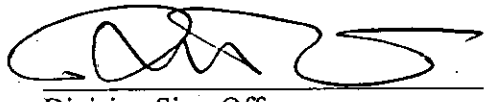
The ***microdot*® *Home*** Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use only), by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is intended for "single patient-home use" only and should not be shared. It should be used only for testing fresh capillary whole blood samples from a fingerstick or palm for glucose (sugar). Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly). It is not intended for use on neonates or in the diagnosis of or screening for diabetes mellitus.

The system consists of the ***microdot*® *Home*** Blood Glucose meter, ***microdot*® *Home*** Test Strips and ***microdot*®** Control solutions.

microdot*® *Home Test Strips
The ***microdot*® *Home*** Test strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick or palm.

Prescription Use _____ And/Or Over the Counter Use **YES**
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
k102383